



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,242	08/31/2001	Marcus Larsson	56450 (45579)	1297

21874 7590 03/27/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 03/27/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,242

Applicant(s)

LARSSON ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 27-61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☒ Claim(s) 27-60 is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) -
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-62 are pending in this application.

Priority

Priority to Denmark Patent application No. PA 2000 01301, filed September 01, 2000, has been acknowledged.

Election/Restrictions

Applicant's election of Group I, claims 1-60, in Paper No. 9, filed December 23, 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 61-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Objections

Claims 27-60 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 27-60 have not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 21, and 23-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claimed invention is drawn to a lung surfactant composition comprising a lung surfactant and although the claims give particular properties of the lung surfactant, these are properties

inherent to the composition itself. Since these claims are drawn to a lung surfactant composition comprising a lung surfactant, they read on a product of nature (i.e. a lung or simply the lung surfactant within the lung).

Claim 26 is also rejected under this statute because the membrane of the lung would further comprise proteins, water, mucus, etc. and would thus also comprise another active substance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 7-8, 11, 13-15, 20, 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74

Art Unit: 1614

(Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation of an ionic strength of at least 10mM, and the claim also recites an ionic strength of at least 15mM, of at least 20mM, of at least 25mM, of at least 50mM, of at least 75mMm of at least 100mM, and of at least 125mM which are narrower statements of the range/limitation.

Furthermore the phrase "such as" renders claim 3 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 4 is rejected for reasons analogous to those of claim 3.

Regarding claim 7, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 8, 11, 13, 15, 23, 24, and 25 are rejected for reasons analogous to those of claim 3.

The term "semi-synthetically" in claim 21 is a relative term, which renders the claim indefinite. The term "semi-synthetically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of "semi-synthetically" are unclear as claimed instantly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Egan et al., 6,129,934 and further in view of Takahashi et al., Biophysical Properties of Protein-Free, Totally Synthetic Pulmonary Surfactants, ALEC and Exosurf, in comparison with surfactant TA. Acta Paediatr Jpn 1994 Dec; 36(6): 613-8.

Egan teaches that since the 1950's lung surfactant has been obtained from all vertebrates, including mammals. The reference teaches many different methods of obtaining surfactant products including methods of obtaining artificial surfactants, natural surfactants, lung tissue surfactants, lung tissue surfactant extracts, recombinant surfactants, and natural surfactant extracts, thus lung surfactant compositions comprising lung surfactants have clearly been known in the prior art. In Table 1, Egan

Art Unit: 1614

et al., teach the preferred embodiment of their invention, wherein the lung surfactant composition comprises DPPC and surfactant apoproteins B and C, thus meeting the specific limitations of instant claims 12 and 13. See: col. 6, line 8 – col. 7, line 46.

The primary reference teaches obtaining the lung surfactant composition from mammalian lungs and adding additional phospholipids to the surface-active material. The Egan et al., reference teaches that the surface-active ingredient, comprising the phospholipid is dried and then resuspended in a sterile saline solution. Finally the reference teaches using the final product for the treatment of lungs and that said treatment could improve lung functions in mammals with respiratory deficiencies. See: col. 10, lines 36-42; col. 12, lines 40-42; col. 13, lines 5-20; col. 17, line 35 – col. 18, line 51; col. 19, line 1- col. 20, line10; and abstract.

Although the primary reference teaches obtaining lung surfactant compositions from mammalian lungs, and lung surfactant compositions comprising the specific proteins and phospholipids as instantly claimed, for treatment of respiratory disorders, Egan et al lack the specific properties as claimed instantly in claims 1-2.

Takahashi et al teach that the surface activity of artificial lung surfactants is improved by the addition of SP-B and SP-C and that these results suggest that a surfactant which contains SP-B and SP-C do not have to be dry or crystalline for an effective exogenous surfactant. See: abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of Egan et al., by adjusting the amounts of SP-B and SP-C to obtain a lung surfactant composition with desired

Art Unit: 1614

biophysical properties as taught by Takahashi et al. Furthermore, Egan et al., teach a lung surfactant composition comprising the same ingredients as claimed, and it would be expected that a composition comprising the same ingredients in the same amounts would have the same effect upon dispersal in an electrolyte and/or sodium chloride solution. However, the instant claims do not require that the lung surfactant be dispersed, thus, the future intended dispersal of the lung surfactant composition appear to be inherent to the composition itself, but an obviousness type rejection has been made herein because the Office does not have the capabilities of testing and comparing the compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

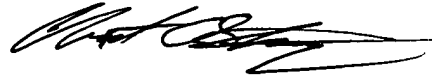
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

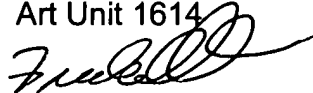
Application/Control Number: 09/945,242
Art Unit: 1614

Page 9

Clinton Ostrup
Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Clinton Ostrup", with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Frederick Krass", with a large, stylized loop at the end.

March 25, 2003